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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
07/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/771,987	SETH ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/14/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-21,25,27-31,33-49,53,55-59,61-76,80,82-85,87-102,105,107-109 and 114-120* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/14/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4-21,25,27-31,33-49,53,55-59,61-76,80,82-85,87-102,105,107-109 and 114-120.

DETAILED ACTION

Previous Claims and Rejections Status

1. Claims 1,2,4-21,25,27-31,33-49,53,55-59,61-76,80,82-85,87-102,105,107-109 and 114-120 are pending in the application. Claims 22-24,26,50-52,54,77-79,81,103-104 and 106 were cancelled in the amendment filed 5/14/09.

2. The rejection of claims 1,2,4-7,11,12,15,17,18,22 and 28-30 under 35 U.S.C. 102(b) as being anticipated by Moeckel et al. (US 5,955,106) is withdrawn due to the amendment to the claims.

3. The rejection of claims 1,2,4,5,7-13,15,17-19,29 and 30 under 35 U.S.C. 102(b) as being anticipated by Cheng et al. (US 6,099,859) is withdrawn due to the amendment to the claims.

Response to Arguments

4. Applicant's arguments filed 5/14/09 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1,2,4-12,19,25-31,33-40,45-47,53-59,61-74,80,82-85,87-100,105-109 and 114 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as stated in the office action mailed 11/14/08.

7. Applicant asserts that the claims are supported by the specification as the identity of the cores and the coatings in various embodiments are described for example in paragraphs [0013-0015]. Dissolution profiles of the tablets are described in paragraph [0013], [0030], and [0031] for example.

8. The examples provided for the dissolution profiles describe only ethylcellulose, povidone, stearic acid/dibutyl sebacate coating formulations and do not describe a representative number of examples of water-insoluble, water-permeable film-forming polymer species; water soluble polymer species; or plasticizer species for the coating formulations. Therefore the specification does not provide a reasonable generic description to support coating formulations which exhibits the dissolution profiles of the instant claims.

New Objection

Claim Objections

9. Claim 114 is objected to because of the following informalities: the instant claim recites, "-114". Appropriate correction is required.

New Grounds of Rejection Necessitated by the Amendment to the Claims

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1,2,4-21,25,27-31,33-49,53,55-59,61-76,80,82-85,87-102,105 and 107-109 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The instant claims 1,31,59 and 85 recite, “3 to 25% by weight of a non-hydrocolloid expanding agent” whereas the specification recites, “from about 3% to about 25%" of the expanding agent (specification, p5, [0015]; p7, [0023]).

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claim 27 recites the limitations " water-insoluble, water-permeable film-forming polymer: water soluble polymer: plasticizer". The instant claim 1 to which claim 27 depends does not recite these limitations. There is insufficient antecedent basis for this limitation in the claim.

14. Applicant's arguments with respect to claims 1,2,4-21,25,27-31,33-49,53,55-59,61-76,80,82-85,87-102,105,107-109 and 114-120 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 1,2,4-21,25,27,29-31,33-49,53,55,57-59,61-76,80,83-85,87-102,105,108 and 109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matharu et al. (US2003/0021841A1) in view of Buhler et al. (US 6,592,900B1) and in further view of Cheng et al. (US 6,099,859) and Oshlack et al. (US 5,472,712).

17. Matharu et al. (US2003/0021841A1) discloses the preparation of metformin HCl tablets with a core comprising metformin HCl (50%) (i.e. 850 mg), microcrystalline cellulose (non-hydrocolloid expanding agent) (32%), magnesium stearate (0.8%), silicon dioxide, excipients, etc. to improve the compressibility of the tablet (abstract; 2, [0022]; p4, [0045-0046]). The process of the disclosure is useful for preparing both immediate release and sustained release tablet dosage forms (p 2, [0024]). Matharu et al. does not disclose crospovidone expanding agent contained in the core or an extended release coating comprising a water-insoluble, water-permeable film-forming polymer species; water soluble polymer species; or a plasticizer.

18. Buhler et al. (US 6,592,900B1) discloses the use of crospovidone as a disintegrant for tablets which is a particularly suitable stabilized disintegrant (column 3, lines 24-26; column 2, lines 42-43).

19. Cheng et al. (US 6,099,859) discloses an extended (controlled or sustained) release pharmaceutical tablet which contains a core of metformin hydrochloride in about 50-98% or 75-95% and commonly known excipients (column 1, preferably lines 8-22; column 3, lines 34-39 and 66+; column 4, lines 8-10; column 5, lines 35-41; example 3).

The pharmaceutical tablet of the disclosure does not contain monomeric pore forming agents and may be coated with a semipermeable membrane. The semipermeable membrane comprises, a hydrophobic polymer (i.e. ethyl cellulose); HPMC or hydroxypropyl cellulose (50-99%); a plasticizer (i.e. stearate, dibutylsebacate) (0 to about 24%), etc. (column 4, lines 10-67; column 5, lines 1-7) .

20. Oshlack et al. (US 5,472,712) discloses a controlled release tablet comprising a core containing an active agent (i.e. therapeutically active agent) coated with a hydrophobic polymer (i.e. ethylcellulose) (column 2, lines 60+; column 3, lines 35-56), a plasticizer (i.e. dibutyl sebacate) (column 8, lines 31+) and a water-soluble polymer/release modifying agents (i.e. polyvinylpyrrolidone) (column 12, lines 54+).

21. At the time of the invention it would have been obvious to one ordinarily skilled in the art to substitute the microcrystalline cellulose non-hydrocolloid expanding agent found in the core of Matharu et al. for the non-hydrocolloid disintegrant/expanding agent (i.e. crospovidone) of Buhler et al. with predictable results, such as disintegration of the tablet core. It is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect.

22. It would have been obvious to one ordinarily skilled in the art to coat the metformin preparation of Matharu et al. with the semipermeable membrane (ethyl cellulose; HPMC and stearate or dibutylsebacate) of Cheng et al. or (ethyl cellulose; polyvinylpyrrolidone and dibutylsebacate) Oshlack et al. as the disclosures are drawn to

the same utility, such as extended (controlled or sustained) release tablet preparations. Therefore the results would be predictable, such as the extended release of the metformin from a tablet core. The semipermeable membranes of Cheng et al. and Oshlack et al. encompasses the coating of the instant claims, see specification p8, [0026]) and therefore have the same properties and are capable of the same functions, such as being designed to provide the dissolution profiles of the instant claims.

23. Claims 1,2,4-9,11-13,15,17-19,27-31,33-37,39-41,43,45-47,55-59,61-64,66-68,70,72-74,82-85,87-90,92-94,96,98-100,107-109 and 114-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matharu et al. (US2003/0021841A1) in view of Buhler et al. (US 6,592,900B1) and in further view of Moeckel et al. (US 5,955,106) and Cheng et al. (US 6,099,859)

24. Matharu et al. (US2003/0021841A1) discloses a preparation of metformin HCl (10-90%) comprising a hydrophilic erodible component/disintegrant (10-90%) (i.e. croscarmellose sodium), a hydrophobic component (1-30%) (i.e. glyceryl behenate), excipients, etc. (p1, [0011]; 2, [0022]). The process of the disclosure is useful for preparing both immediate release and sustained release tablet dosage forms (p 2, [0024]). Matharu et al. does not disclose crospovidone expanding agent and polyvinyl alcohol in the core or an extended release coating comprising a water-insoluble, water-permeable film-forming polymer species; water soluble polymer species; or a plasticizer.

25. Buhler et al. (US 6,592,900B1) discloses the use of crospovidone as a disintegrant for tablets which is a particularly suitable stabilized disintegrant (column 3, lines 24-26; column 2, lines 42-43).

26. Moeckel et al. (US 5,955,106) discloses an extended release pharmaceutical tablet that contains a core of metformin hydrochloride in about 70-95% (i.e. 850 mg) (column 3, lines 8-13; column 4, lines 23-24); polyvinyl alcohol and excipients, such as magnesium stearate (stearic acid), silicon dioxide (column 2, lines 20-30; column 4, line 35) where the core is further coated with a film. The active substance can be delayed by the film that is formed which may contain pore formers but does not necessarily contain such pore formers (column 4, lines 6-9). The film coating comprises a film forming polymer, such as ethyl cellulose (column 3, lines 53-57; column 4, lines 1-9; column 5, lines 13-14; example 1).

27. Cheng et al. (US 6,099,859) discloses an extended (controlled or sustained) release pharmaceutical tablet which contains a core of metformin hydrochloride in about 50-98% or 75-95% and commonly known excipients (column 1, preferably lines 8-22; column 3, lines 34-39 and 66+; column 4, lines 8-10; column 5, lines 35-41; example 3). The pharmaceutical tablet of the disclosure does not contain monomeric pore forming agents and may be coated with a semipermeable membrane. The semipermeable membrane comprises, a hydrophobic polymer (i.e. ethyl cellulose); HPMC or hydroxypropyl cellulose (50-99%); a plasticizer (i.e. stearate, dibutylsebacate) (0 to about 24%), etc. (column 4, lines 10-67; column 5, lines 1-7) .

28. At the time of the invention it would have been obvious to one skilled in the art to substitute the croscarmellose sodium disintegrant/expanding agent of Matharu et al. for the non-hydrocolloid disintegrant/expanding agent of Buhler et al. with predictable results, such as disintegration of the tablet core. It is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect. It would also have been obvious to one skilled in the art to include commonly used excipients in the core of Matharu et al. as the metformin preparations of Matharu et al. and Cheng et al. teach that additional excipients may be included in the core (i.e. silicon dioxide, PVA, etc.).

29. It would have been obvious to one ordinarily skilled in the art to coat the metformin preparation of Matharu et al. with the semipermeable membrane comprising ethyl cellulose; HPMC and stearate or dibutylsebacate of Cheng et al. as both disclosures are drawn to the same utility, such as extended (controlled or sustained) release tablet preparations. The semipermeable membrane of Cheng et al. encompasses the coating of the instant claims, see specification p8, [0026]) and therefore has the same properties and is capable of the same functions, such as being designed to provide the dissolution profiles of the instant claims.

Conclusion

No claims are allowed at this time.

30. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618